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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/055,747      | 01/23/2002  | Lixiao Wang          | S63.2-10062         | 7360             |

490 7590 12/19/2003

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

NOLAN, SANDRA M

ART UNIT PAPER NUMBER

1772

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/055,747

Applicant(s)

WANG ET AL.

Examiner

Sandra M. Nolan

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2003 and 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 15-27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-17 and 29-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 7. 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claims***

1. Following the office action dated 24 June 2003 (Paper No. 3) and applicants' amendment in their 26 September 2003 response (Paper No. 6), claims 1-13, 15-27 and 29-34 are pending.

### ***Information Disclosure Statement***

2. The information disclosure statements (IDS's) submitted on 17 July and 26 September 2003 (Paper Nos. 4 and 7, respectively) were considered by the examiner.

### ***Rejections Withdrawn***

3. All of the 35 USC 112 and 35 USC 103 rejections made in Paper No. 3 have been withdrawn in response to applicants' amendments and arguments on pages 1-12 of Paper No. 6.

4. New rejections of all of the now-pending claims are recited below.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3, 5-13, and 15-16 are rejected under 35 U.S.C. 103(a) as being obvious over Moroni (US 6,426,145) in view of the Scholtens et al disclosure (Reference CA on Paper No. 7) and Loontjens et al (US 6,228,980).

The Moroni reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

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Moroni teaches medical devices bearing coatings (abstract) based on compositions containing high molecular weight polyamides (abstract; claim 2 of the patent at col. 5, line 66) or polyesters (claim 2 of the patent at col. 5, line 66) and a reactive chain extender (claim 1 of the patent at col. 5, lines 57-61). They are used to coat catheters and balloons (col. 5, lines 8-9).

Moroni's coating compositions, when in place on devices, are deemed to be part of the medical devices, so that the devices are "formed from" its compositions.

Moroni fails to teach the chain extenders recited in applicants' claims.

Scholtens teaches the use of chain extended polyamides (PA) and polyester (PET for polyethylene terephthalate) in Slide 18. The extended materials have high molecular weights that give them better mechanical properties and make them suitable as engineering plastics applications (Slide 2). The extenders are carbonyl bis-caprolactam (CBC) and 1,4-phenylene bisoxazoline (1,4-PBO) (Slide 8). The extenders are added during processing of the PA or PET (Slide 10), so that no extra processing step and single screw extruders can be used (Slide 6).

The Loontjens patent teaches that 1,3-PBO, CBC and N,N'-isophthaloyl biscaprolactam (IBC) are useful chain extenders for polyamides and PET (col. 3, lines 2-15). The polyamides and polyesters made have high molecular weights (col. 1, lines 5-6). The compositions are melt mixed with the chain extenders (col. 2, lines 43) and extrusion molded to make articles (col. 5, lines 7-8). Its process gives higher molecular weight polymers very quickly (col. 1, lines 48-52).

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The references are analogous because they all deal with chain extended polyamides and polyesters and articles made therefrom.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the chain extenders of Scholtens and the Loontjens patent, or analogs thereof, in the compositions of Moroni in order to increase the molecular weights of the polyamides and polyesters therein and, thereby enhance the mechanical properties thereof without lengthening the processing needed to make the Moroni balloons.

The motivation to employ the chain extenders of Scholtens and Loontjens in the compositions of Moroni is found at Slide 2 of Scholtens and at col. 1, lines 48-52 of the Loontjens patent, where improved mechanical properties and quick reaction are taught.

It is deemed desirable to make medical devices using plastics that have improved mechanical properties so to product integrity is insured when they are placed inside patients' bodies.

It is deemed desirable to make medical devices quickly to improve manufacturing efficiency and profits.

8. Claims 1-13, 15-27 and 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US 5,554,120) in view of the Scholtens et al disclosure (Reference CA on Paper No. 7) and Loontjens et al (US 6,228,980).

Chen teaches that polyamides having molecular weights in excess of 5,000 can be blended with polyolefins to give compositions that produce medical devices having improved burst pressures (abstract). The compositions are used to make dilatation

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balloons (col. 1, line 14). Balloon tubing is made via extrusion (col. 8, lines 6-9). The balloons made have better handling properties than PET (col. 7, lines 52-54).

Chen fails to teach the use of the chain extended polyamides.

Scholtens and the Loontjens patent are discussed above. Note, also, that Loontjens teaches chain extended polyamides having molecular weights of 15,000 or more at col. 5, lines 1-5.

The extrusion blending and reaction features of applicants' process claims are taught by Scholtens and the Loontjens patent.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the chain extended polyamides of Scholtens and the Loontjens patent, or analogs thereof, to make the balloons of Chen in order to improve the mechanical properties of the balloons (per Scholtens) and shorten production times (per Loontjens).

The motivation to employ the chain extenders of Scholtens and Loontjens to make the balloons of Chen is found at Slide 2 of Scholtens and at col. 1, lines 48-52 of the Loontjens patent, where improved mechanical properties and quick reaction are taught.

It is deemed desirable to make medical devices using plastics that have improved mechanical properties so to product integrity is insured when they are placed inside patients' bodies.

It is deemed desirable to make medical devices quickly to improve manufacturing efficiency and profits.

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***Response to Arguments***

9. Applicant's arguments with respect to claims 1-13 and 15-27 and 29-32 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication should be directed to the Examiner, Sandra M. Nolan, whose telephone number is 703/308-9545. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the Examiner by telephone are unsuccessful, her supervisor, Harold Pyon, can be reached at 703/308-4251. The general fax number for the art unit is 703/872-9306. The receptionist answers 703/308-0661.



S. M. Nolan  
Patent Examiner  
Technology Center 1700

SMN/smn  
10055747(8)  
16 December 2003